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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,196	07/23/2003	Guido Guglielmi	03-276 (US01)	1254

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EXAMINER
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YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/04/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/625,196

Applicant(s)

GUGLIELMI ET AL.

Examiner

Diane Yabut

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 29-52,54,55 and 57-71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-52,54,55 and 57-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

This action is in response to applicant's amendment received on 10 January 2007. The examiner acknowledges the changes made to the specification and the amendments to the claims.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 29-36, 44-46, 54-55, 57-61, and 64-65 are rejected under 35 U.S.C. 102(b) as being anticipated by **Scheldrup** (U.S. Patent No. **5,669,905**).

Claim 29: Scheldrup discloses a catheter **158** having a proximal end and a distal end, the catheter being capable of being inserted into a vascular cavity in the body, a delivery member **102**, a temporary connection **106** joining an implant and a distal end of the delivery member, and an electrical measurement device, wherein the electrical measurement device is configured to monitor an electrical condition related to a position of the temporary connection while the temporary connection is joined to the implant and delivery member, the electrical condition changing when the temporary connection reaches a predetermined location as the delivery member is advanced through the catheter, the electrical

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measurement device configured to generate an output signal in response to the changed electrical condition, the output signal indicating that the temporary connection has reached the predetermined location (Figures 3-5, and col. 4, lines 1-33 and col. 6, lines 36-62 and col. 7, lines 39-48, col. 10, lines 30-44).

Claims 30-31: Scheldrup discloses the delivery member comprising a delivery wire, or a tubular body **102** (Figure 3).

Claim 32: Scheldrup discloses the temporary connection comprising an electrolytic connection (col. 4, lines 34-42).

Claim 33: Scheldrup discloses a power supply **170** configured to provide electric current, the electrolytic connection being broken by current provided by the power supply through the delivery member and the temporary connection to corrode a portion of the temporary connection (Figures 4-5, and col. 4, lines 1-24).

Claim 34: Scheldrup discloses the corrodible portion of the temporary connection being corroded comprising a stainless steel portion of the delivery member that is exposed to blood in the vascular cavity in the body (col. 5, lines 49-55).

Claims 35-36: Scheldrup discloses the electrical monitoring device **300** being included in ("integrated with") the power supply and separate from the power supply (Figures 6-7 and col. 5, lines 1-3).

Claims 44-45: Scheldrup discloses the implant comprising a vaso-occlusive implant, which also comprises a coil (col. 1, lines 1-19 and col. 6, lines 1-11).

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Claim 46: Scheldrup discloses the coil comprising a Guglielmi Detachable Coil (GDC) (col. 12, lines 19-33).

Claims 54-55: Scheldrup discloses a visual indicator, the electrical measurement device being configured to provide the output signal to the visual indicator so that the visual indicator can be illuminated after the electrical condition has changed (Figure 6 and col. 7 line 49 to col. 8, line 33), and an audio indicator, the electrical measurement device being configured to provide the output signal to the audio indicator so that the audio indicator can be activated after the electrical condition has changed (col. 10, lines 30-44).

Claim 57: Scheldrup discloses the output signal being provided to a controller **300**, the electrical measurement device being configured to provide the output signal to the controller, the controller being configured to automatically break the temporary connection in response to the output signal after the electrical condition has changed (Figure 6, col. 8, lines 40-49).

Claim 58: Scheldrup discloses insulative members **112** and **110** (Figure 2, col. 6, lines 1-22). Although Scheldrup does not disclose an insulation member between the implant and the temporary connection, it would have been obvious to one of ordinary skill in the art to provide an insulation member between the implant and the temporary connection to focus electrolysis on a targeted, specific location.

Claims 59-61: Scheldrup discloses the predetermined position comprising the distal end of the catheter and the electrical condition changing when the

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temporary connection reaches or extends beyond the distal end of the catheter (col. 7, lines 20-48).

Claims 64-65: Scheldrup discloses a conductive wire connected between the electrical measurement device and the distal end of the catheter, the conductive wire being inserted through the catheter, the electrical measurement device being configured to detect an electrical condition related to a position of the temporary connection in the catheter through the conductive wire, and the electrical monitoring device comprising a volt/current meter (Figures 4-6).

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Scheldrup** (U.S. Patent No. **5,669,905**), as applied to Claim 29 above, and further in view of **Palermo** (U.S. Patent No. **5,250,071**).

Claim 37: Scheldrup discloses the claimed device as discussed above, except for a temporary mechanical connection.

Palermo teaches an embolic coil with a temporary mechanical connection (col. 2, lines 63-67 and col. 3, lines 1-18). It would have been obvious to one of ordinary skill in the art to provide a temporary mechanical connection, as taught

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by Palermo, to Scheldrup, since it was known in the art that temporary mechanical connections are common in detachable surgical implants that extend to filters and stents.

4. Claims 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Scheldrup** (U.S. Patent No. **5,669,905**), as applied to Claim 29 above, and further in view of **Guglielmi** (U.S. Patent No. **5,569,245**).

Claims 38-39: Scheldrup discloses the claimed device, as discussed above, except for the temporary connection comprising a temporary connection that is breakable by application of heat and radio frequency (RF) radiation.

Guglielmi teaches a temporary connection that is breakable by application of heat and radio frequency (RF) radiation (col. 3, lines 10-20). It would have been obvious to one of ordinary skill in the art to provide a temporary connection broken by heat and RF radiation, as taught by Guglielmi, to Scheldrup, since it was known in the art that heat and RF radiation are effective detachment sources and commonly break connections, joints, or attachments in surgical devices.

5. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Scheldrup** (U.S. Patent No. **5,669,905**), as applied to Claim 29 above, and further in view of **Sepetka** (U.S. Patent No. **5,814,062**).

Claim 40: Scheldrup discloses the claimed device as discussed above, except for the temporary connection comprising a temporary connection that is hydraulically broken.

Sepetka teaches a temporary connection that is hydraulically broken (col. 3, lines 10-26). It would have been obvious to one of ordinary skill in the art to provide a temporary connection that is hydraulically broken, as taught by Sepetka, to Scheldrup, since it was known in the art that fluid pressure is commonly used to disconnect temporary detachments between embolic coils and delivery members..

6. Claims 41-43, and 47-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Scheldrup** (U.S. Patent No. **5,669,905**), as applied to Claim 29 above.

Claims 41-43: Scheldrup discloses the electrical condition comprising an impedance (col. 4, lines 1-24). Although Scheldrup does not disclose the electrical condition being current in this embodiment, Scheldrup acknowledges that in another example, current may be monitored (col. 12, lines 42-46).

Claims 47-50: Scheldrup discloses the coil including platinum (col. 5, lines 38-50). Although Scheldrup does not disclose the coil having a bio-reactive material coating or the coil being a non-bio-reactive polymer coil, it would have been obvious to one of ordinary skill in the art to provide the claimed materials, since it was known in the art that a coating of bio-reactive material may aid in the endovascular embolism or occlusion and non-bio-reactive polymer coils can remain longer within the body without having to be surgically removed.

Claims 51-52: Scheldrup discloses the claimed device except for the implant comprising a stent or a filter. It would have been obvious to one of ordinary skill



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in the art to provide a stent or a filter as the implant, since it was known in the art that vaso-occlusion is commonly achieved by filters and stents.

7. Claims 62-63, 67-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Scheldrup** (U.S. Patent No. **5,669,905**), as applied to Claim 29 above, and further in view of **Cheng** (U.S. Patent No. **6,296,636**).

Claims 62-63 and 67: Scheldrup discloses the claimed device as discussed above (see paragraphs 1 and 6 and Figure 11 and col. 11, lines 24-34), including measuring an electrical current as the delivery member is pushed through the catheter and the electrical current being related to a relative position of the temporary connection before the temporary connection is broken (when it is at a pre-determined location), except for the electrical measurement device including a current measurement device configured to monitor the electrical current and a comparison circuit, the electrical current being related to a relative position of the temporary connection before the temporary connection is broken, the comparison circuit being configured to compare a reference or threshold current to a second current measured by the electrical measurement device, the comparison circuit being further configured to generate the output signal when the temporary connection has reached the predetermined location and the measured current or second current is larger than the reference or threshold current.

Cheng teaches an electrical measurement device including a current measurement device configured to monitor the electrical current and a

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comparison circuit, the comparison circuit being configured to compare a threshold current to a current measured by the electrical measurement device, the comparison circuit being further configured to generate the output signal when the temporary connection has reached the predetermined location and the measured current is larger than the threshold current – the output indicating limiting power (col. 5, lines 15-34). Cheng teaches that limiting power during electrosurgery to avoid overcurrents or sparks that may occur is effectively prompted by using reference and measured currents (col. 3, lines 48-55). It would have been obvious to one of ordinary skill in the art to provide an electrical measurement device including a comparison circuit that compares a threshold current to a current measured by the electrical measurement device which is larger than the threshold current, as taught by Cheng, to Scheldrup in order to obtain a desired output signal, which may limit power during electrosurgery to avoid overcurrents or sparks, which is effectively prompted by using reference and measured currents.

Claim 68: Scheldrup discloses the temporary connection can be broken electrolytically after the output signal is generated (col. 4, lines 34-42).

Claims 69-70: Scheldrup discloses a visual indicator, the electrical measurement device being configured to provide the output signal to the visual indicator so that the visual indicator can be illuminated after the electrical condition has changed (Figure 6 and col. 7 line 49 to col. 8, line 33), and an audio indicator, the electrical measurement device being configured to provide

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the output signal to the audio indicator so that the audio indicator can be activated after the electrical condition has changed (col. 10, lines 30-44).

Claim 71: Scheldrup discloses the output signal being provided to a controller 300, the electrical measurement device being configured to provide the output signal to the controller, the controller being configured to automatically break the temporary connection in response to the output signal after the electrical condition has changed (Figure 6, col. 8, lines 40-49).

### ***Response to Arguments***

8. Applicant's arguments filed 10 January 2007 have been fully considered but they are not persuasive.

9. Applicant generally argues that there is a main distinction between the primary reference of Scheldrup and the present invention. The applicant argues that the output signal in response to a changed electrical condition results from, or follows, breaking of a temporary connection in Scheldrup and is distinct from the present invention's output indicating a temporary connection is positioned at a particular, pre-determined location wherein it can be subsequently broken. The examiner disagrees. As maintained above, the output signal in Scheldrup indicates that the temporary connection is located in a predetermined site and may not necessarily be broken, and that the visual signals are seen before the separation has occurred (col. 4, lines 25-33, col. 7 line 49 to col. 8, line 33).

Applicant argues Scheldrup failing to disclose a visual signal, which is

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moot in view of the new ground of rejection (in paragraphs 1 and 7). The argument of Scheldrup failing to disclose an audio indicator after an electrical condition has changed because the beeps are being emitted after the coil has been attached is not persuasive since the recitation of the claim is "after the electrical condition has changed," which coincides around the time the coil has been detached.

Applicant also argues that Scheldrup does not disclose the electrical measurement device being configured to compare a reference current with a second current that is larger than the reference current. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references, and the limitations are rejected over Scheldrup in view of Cheng, as maintained above. Cheng is directed to the same problem-solving area of using both reference and measured currents to prompt or indicate a condition to the surgeon, and therefore it would have been obvious to one of ordinary skill in the art to use this teaching.

Lastly, applicant argues that Palermo, Gugliemi, and Sepetka do not cure the deficiencies of Scheldrup. The examiner disagrees and maintains the references read on the limitations in Claim 37-40 in paragraphs 3-5 above.

### ***Conclusion***

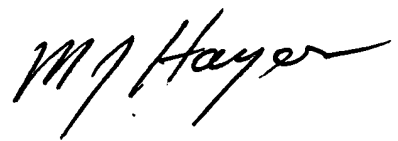
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

A handwritten signature in black ink, appearing to read "M J Hayes", with a stylized flourish at the end.

MICHAEL J. HAYES  
SUPERVISORY PATENT EXAMINER